REMARKS

Claims 1 – 8, 10 – 22, 24 – 28 and 30 -32 are pending in this application with claims 1 – 3 and 20 being withdrawn from consideration. Claims 4, 5, 10, 13, 18, 21, 30, 32 and 33 being amended by this response. Specifically claims 4, 5, 10, 13, 18, 21, 30, 32 and 33 are formally amended for purposes of clarity to state that "upon application by a user said composition is able to abrade the site and circulate at least one of a toxin and venom out from said site". Support for this amendment can be found in the specification on page 6, lines 5 – 8; page 7, lines 8 – 11; and on page 13, lines 5 – 12. Claims 13 and 18 were further formally amended to correct typographical spelling errors inadvertently contained therein as well as to add "methylparaben" as an accepted "water based carrier" for use in the composition of the present invention. Support for "methylparaben" as a carrier is found on page 10, line 13 of the specification. Thus, it is respectfully submitted that no new matter is added by this response.

Rejection of Claims 4-8, 10 – 19, 21 – 22, 24 – 28 and 30 - 32 under 35 U.S.C. 112, first paragraph

Claims 4-8, 10 – 19, 21 - 22, 24 – 28 and 30 – 33 stand rejected under 35 U.S.C. 112, first paragraph as not meeting the enablement requirement. Applicant assumes that the Examiner intended to reject claim 33 on the same grounds and thus the arguments regarding claim 33 are included in this response.

The present invention recites a pharmaceutical composition for topical application to a site of insect bites and stings to relieve any of itch, pain, and swelling associated therewith. The composition consists of an effective amount of an abrasive ingredient and a carrier. Upon application by a user, the composition is able to abrade the site and circulate at least one of a toxin and venom out from the site. The abrasive ingredient is selected

from the group consisting of walnut shell, pumice, plastic material, sand, stone, glass, seed shell, fruit shell, seed, metal, chitosan and ground crab shell and the carrier is selected from the group consisting of vegetable oil, fruit oil, soap, surfactant, lubricant, mineral oil, petrolatum, gel, lotion, emollient, white petroleum, beeswax, di-propylene glycol, gum, lubricating jelly and olive oil. Independent claims 10, 21 and 30 include similar limitations as discussed above.

The Examiner rejected claims 4 – 8, 10 – 19, 21 – 22, 24 – 28 and 30 - 33 as not being enabling for "A pharmaceutical composition...consisting of an effective amount of an abrasive ingredient and a carrier, wherein upon application by a user said composition is able to abrade the site and circulate at least one of a toxin and venom out from said site". Applicant respectfully disagrees with the Examiner.

Specifically, as stated throughout the specification, the composition consisting of an effective amount of abrasive ingredient and a carrier is able to contact and draw out any foreign body deposited at a site of an insect bite (see specification page 6, lines 5 – 8 and page 7, lines 8 – 11). Furthermore, as stated on page 13, lines 5 – 12, the pharmaceutical composition having "an abrasive action" is able to be applied to a site of an insect bite and/or sting. Upon applying the composition to the site of an insect bite or sting effective relief is had within seconds as "the allergenic material can be withdrawn rapidly from the body before getting into the bloodstream". Therefore, Applicant respectfully submits that the present specification fully enables the present pharmaceutical composition, "wherein upon application by a user said composition is able to abrade the site and circulate at least one of a toxin and venom out from said site".

The Examiner further erroneously states that there is not one working example in the specification that demonstrates that any of the claimed composition which include abrasive ingredients and carriers such as gum or a lubricant will actually perform

commensurate in scope with the present claimed invention and further cites the record of prior art. Applicant respectfully submits that the Examiner fundamentally misunderstands the present claimed invention. Specifically, the Examiner states that the carriers listed by Applicant are not know for circulating toxins and venoms out from said site but rather are used to texturize products for easy topical delivery. With that contention, the Applicant agrees. The carriers alone do not abrade and circulate at least one of a toxin and venom out from said site. Rather, it is the "pharmaceutical composition for topical application to a site of insect bites and stings...consisting of an effective amount of an abrasive ingredient and a carrier, wherein upon application by a user said composition is able to abrade the site and circulate at least one of a toxin and venom out from said site". The emollients and other carriers listed in the present claimed invention are cited for combination with "an effective amount of abrasive ingredient" and not intended to be used alone. No current claims recite "a carrier able to abrade and circulate at least one of a toxin and venom out from said site". All current claims specifically recite "wherein upon application by a user said composition is able to abrade and circulate at least one of a toxin and venom out from said site".

Applicant respectfully submits that the Examiner further erroneously states that the state of the art is unpredictable. Firstly, Applicant respectfully disagrees that there is no disclosure of a compound that is able to contact the toxin or venom produced by an insect bite or sting. As discussed above on page 7 of the present specification, when the "pharmaceutical composition" as claimed in the present invention is "rubbed on the bite or sting affected area...the abrasive ingredient actually draws the allergenic or poisonous substance from the affected area along with any body materials resulting from swelling or infection". Therefore, Applicant submits that it is clearly described that upon "topical application to a site...said composition is able to abrade the site and circulate at least one of a toxin and venom out from said site".

Additionally, Applicant does not understand the Examiner's citation of compounds for cleaving specific toxins. The present claimed invention is concerned with removal of toxins from a cite and not breaking down of toxins as intimated by the Examiner. Applicant agrees that any cleaved toxins would not be able to physically leave the site without manual removal. However, this is not the thrust or intention of the present claimed invention. In fact, the "pharmaceutical composition...consisting of an effective amount of an abrasive ingredient and a carrier" operate to "effectively draw the acids, mucoids, poisons, and similar debris from the site...[which]...are then absorbed, neutralized and diluted in the composition" (see page 9, lines 16 – 20).

Furthermore, applicant respectively submits that the Examiner's assertion that the state of the art is unpredictable is contradicted by the Examiner's citation of Lee (WO 99/37287). In fact, the Examiner states that the present claimed invention is anticipated by Lee which discloses bioactive glass (an perceived abrasive) in combination with a lotion (a carrier) for treating inflammatory skin disorders. As will be shown later, Lee neither discloses nor suggests the present claimed invention, but by virtue of the Examiner's citation of a reference including bioactive glass for use in a lotion clearly shows that the state of the art is quite predictable. This citation clearly implies that the Examiner believes the bioactive glass is an abrasive. While Applicant respectfully disagrees with this contention (for reasons that will be discussed hereinbelow with regard to the rejection under 35 USC 102(b)), then use of abrasives in a lotion to treat skin inflammations are known. Therefore, as the state of the art is predictable and there would be no need to perform expensive, rigorous trial and error protocol as asserted by the Examiner. Additionally, the Examiner provides no evidence or reason as to why said undue experimentation need be performed to ascertain the present claimed "pharmaceutical composition for topical application to a site of insect bites and stings...consisting of an effective amount of an abrasive ingredient and a carrier, where said composition is able to abrade the site and circulate at least one of a toxin and venom out from said site".

Applicant also further respectfully submits that as the carriers listed in each of the rejected claims have been considered previously on the merits by the Examiner and that these carriers are fully supported throughout the specification (see pages 6 – 10 of the present specification), and further that these carriers are clearly disclosed to be combined with the claimed abrasive ingredients that no new matter is contained within the present application.

In view of the above remarks, it is respectfully submitted that the present specification fully enables claims 4 – 8, 10 – 19, 21 – 22, 24 – 28 and 30 – 32 as required under 35 USC 112, first paragraph. Thus, it is further respectfully submitted that this rejection has been satisfied and should be withdrawn.

Rejection of Claims 4, 6, 10, 11, 21, 22, 24, 25, 26, 30, and 31 under 35 USC 102(b)

Claims 4, 6, 10, 11, 21, 22, 24, 25, 26, 30, and 31 stand rejected under 35 USC 102(b) as being anticipated by Lee (WO 99/37287) for reasons stated in the Office Action

The present invention recites a pharmaceutical composition for topical application to a site of insect bites and stings to relieve any of itch, pain, and swelling associated therewith. The composition consists of an effective amount of an abrasive ingredient and a carrier. Upon application by a user, the composition is able to abrade the site and circulate at least one of a toxin and venom out from the site. The abrasive ingredient is selected from the group consisting of walnut shell, pumice, plastic material, sand, stone, glass, seed shell, fruit shell, seed, metal, chitosan and ground crab shell and the carrier is selected from the group consisting of vegetable oil, fruit oil, soap, surfactant, lubricant, mineral oil, petrolatum, gel, lotion, emollient, white petroleum, beeswax, di-propylene glycol, gum, lubricating jelly and olive oil. Independent claims 10, 21 and 30 include similar limitations

as discussed above.

Lee discloses a method for treating inflammatory symptoms such as burning, redness, itching and swelling and pain which accompany skin disorders other than wounds of the skin. The method includes topical application of a medicinal composition comprising a non-interlinked particulate bioactive glass mixed with a topical medicinal carrier to the side of the skin disorder. However, the composition as disclosed by Lee requires that the "particulate bioactive glass and the carrier are mixed before application to the skin." (see Lee, page 5, lines 7 – 8). This is unlike the present claimed invention which is a prepared "composition consist[ing] of an effective amount of an abrasive ingredient and a carrier". Furthermore, Lee states "if the two ingredients are mixed several days prior to application, e.g. one week, the ability of the composition to mitigate the inflammation may be comprised. This problem is particularly acute if the carrier causes bioactive glass to pre-react in a way that reduces the bioactivity of the glass." (see Lee, page 5, lines 8 – 12). Therefore, Lee clearly relies on a specific property of the glass, bioactivity, in order for the invention as disclosed therein to function properly. Lee defines bioactive glass as "glass material having an oxide of silicon as a major component and capable of bonding with growing tissue when reacted with physiological fluids" (see Lee, page 2, lines 17 – 19). Therefore, the bioactive glass of Lee is not analogous to the abrasive ingredient disclosed by the present claimed invention. While the abrasive ingredient of the present claimed invention includes glass, the function of the glass of the present claimed invention is to "abrade the site and circulate out at least one of a toxin and venom from said site". This circulation "relieves any of itch, pain and swelling" which results from an insect bite. The bioactive glass of Lee is a healing agent which biologically bonds with growing tissue and is thus wholly unlike the "abrasive ingredient" of the present claimed invention which is "able to abrade the site".

Furthermore, Lee merely discloses "optionally, with gentle massage, to work the

composition into the skin" (see Lee, page 6, lines 5 – 7). Lee neither discloses nor suggests a pharmaceutical "composition consisting of an effective amount of an abrasive ingredient and a carrier, wherein upon application by a user said composition is able to abrade the site and circulate at least one of a toxin and venom out from said site" as in the present claimed invention.

Additionally, as stated in Lee on page 6, lines 3- 4, the composition disclosed by Lee is applied in a "treatment regimen...at the discretion of an attending medical practitioner". This is also unlike the present claimed invention which is selectively applied by any person who has been bitten or stung by an insect.

Also, Lee states on page 6, lines 1 – 2 that the composition is administered to a patient in a manner similar to that use for the administration of topical anti-inflammatory compositions now in clinical use. However, as discussed above, Lee neither discloses nor suggests a "pharmaceutical carrier...consisting of an effective amount of abrasive ingredient and a carrier, wherein upon application by a user said composition is able to abrade the site" as in the present claimed invention. Lee also neither discloses nor suggests to "circulate at least one of a toxin and venom out from said site" as in the present claimed invention. As a composition "able to abrade the site and circulate at least one of a toxin and venom out from said site" is contrary to the method of administering topical inflammatory compositions used by Lee, applicant respectfully submits that Lee cannot possibly anticipate the pharmaceutical composition of the present claimed invention.

It is respectfully submitted that in view of the above remarks and amendments to claims, that there is no 35 USC 112 enabling disclose present in Lee that anticipates the present invention as claimed in claims 4, 10, 21 and 30. As claim 6 is dependent on claim 4, claim 11 is dependent on claim 10, claims 22 – 26 are dependent on claim 21 and claim 31 is dependent on claim 30, it is respectfully submitted that claims 6, 11, 22 – 26 and 31

are patentable for the same reasons discussed above regarding claims 4, 10, 21 and 30. Thus, it is respectfully submitted that this rejection has been satisfied and should be withdrawn.

Rejection of Claims 7, 8, 27 and 28 under 35 USC 103(a)

Claims 7, 8, 27 and 28 stand rejected under 35 USC 103(a) as being unpatentable over Lee (WO 99/37287) as applied to claims 4, 6, 10, 11, 21, 22, 25, 26, 30 and 31 for the reasons stated in the Office Action.

The Examiner states that while Lee did not specifically teach the bioactive glass being formulated into an aqueous carrier, or as a paste, Lee states that the bioactive glass and topical treatment can be combined in any pharmaceutically acceptable carrier to facilitate application to the skin. However, as discussed above, Lee neither discloses nor suggests a "pharmaceutical composition...consisting of an effective amount of an abrasive ingredient and a carrier, wherein upon application by a user said composition is able to abrade the site" as in the present claimed invention. Furthermore, Lee neither discloses nor suggests to "circulate at least one of a toxin and venom out from said site" as in the present claimed invention. Additionally, the arguments presented above regarding the rejection under 35 USC 102(b) are applicable to the rejection of claims 7, 8, 27 and 28.

It is respectfully submitted that in view of the above remarks that there is no 35 USC 112 enabling disclose present in Lee that makes the present invention as claimed in claims 4, 10, 21 and 30 unpatentable. As claims 7 and 8 are dependent on claim 4 and claims 27 – 28 are dependent on claim 21, it is respectfully submitted that claims 7, 8, 27 and 28 are patentable for the same reasons discussed above regarding claims 4 and 21. Thus, it is respectfully submitted that this rejection has been satisfied and should be withdrawn.

Rejection of Claims 5, 12 – 19 and 32 under 35 USC 103(a)

Claims 5, 12 – 19, and 32 stand rejected under 35 USC 103(a) as being unpatentable over Lee (WO 99/37287) as applied to claims 4, 6, 10, 11, 21, 22, 25, 26, 30 and 31, and further in view of Rubin (U.S. 5,543,149) for the reasons stated in the Office Action.

As discussed above, Lee neither discloses nor suggests a "pharmaceutical composition...consisting of an effective amount of an abrasive ingredient and a carrier, wherein upon application by a user said composition is able to abrade the site and circulate at least one of a toxin and venom out from said site" as in the present claimed invention. In fact, the composition disclosed by Lee is more akin to a healing agent as the bioactive glass includes certain properties that allow tissue to bond therewith and thus is not an abrasive ingredient as claimed in the present invention.

Rubin discloses a method of treating insect bites with digestive enzymes such as papain and pancreatin. However, similarly to Lee, Rubin neither discloses nor suggests a composition including "an effective amount of abrasive ingredient and a carrier, wherein upon application by a user said composition is able to abrade the site" as in the present claimed invention. Furthermore, Rubin neither discloses nor suggests to "circulate at least one of a toxin and venom out from said site" as in the present claimed invention. Additionally, Rubin specifically discloses a method for reducing the itch associated with the bite of a blood feeding insect such as a mosquito or black fly. The pharmaceutical composition of the present claimed invention includes "an abrasive ingredient...and a carrier...wherein upon application by a user said composition is able to abrade the site and circulate at least one of a toxin and venom from said site" (of the insect bite). Therefore,

the composition of Rubin is meant for treating a different ailment than the pharmaceutical composition of the present claimed invention.

Additionally, Applicant respectfully submits that even if the composition of Lee was combined with the composition of Rubin, the resulting composition would not be a "pharmaceutical carrier...consisting of an effective amount of an abrasive ingredient and a carrier, wherein upon application by a user said composition is able to abrade the site and circulate at least one of a toxin and venom out from said site" as in the present claimed invention. Rather, the resulting composition would be a lotion having bioactive glass and papain that, upon application increases the healing of the wound due to the properties of the bioactive glass while simultaneously reducing the itch and discomfort of the wound. Furthermore, this lotion would be specifically suited to mitigate the effects of a blood feeding insect and help heal any wound associated therewith. This resulting composition would not be suitable for treating "a site of insect bites and stings to relieve any of itch pain and swelling associated therewith" as in the present claimed invention. Additionally, a composition produced by the combination of Lee and Rubin would not be "able to abrade the site and circulate at least one of a toxin and venom out from said site" as in the present claimed invention. As the combination of Lee with Rubin produces a fundamentally different composition than the composition of the present claimed invention, it would not be obvious to combine Lee with Rubin to produce the present claimed invention.

In view of the above remarks Rubin when taken alone or in combination with Lee provides no 35 USC 112 enabling disclosure that makes the present invention as claimed in claims 5, 13, 18 and 32 unpatentable. As claim 12 is dependent on claim 5, claims 14 – 17 are dependent on claim 13 and claim 19 is dependent on claim 18, it is respectfully submitted that claims 5, 14 – 17 and 19 are patentable for the same reasons as discussed above regarding claims 5, 13 and 18 respectively. Thus, it is further respectfully submitted that this rejection has been satisfied and should be withdrawn.

No additional fee is believed due with this response. However, should a fee be due please charge the fee to Deposit Account No. 50-2828.

Based upon the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner consider necessary or desirable any formal changes anywhere in the specification, claims and/or drawings, then it is respectfully asked that such changes be made by Examiner's amendment, if the Examiner feels this would facilitate passage of the case to issuance.

Alternatively, should the Examiner have any questions, comments, or feel that a personal discussion might be helpful in advancing this case to allowance and issuance, she is cordially invited to contact Mr. Jack J. Schwartz at 1350 Broadway, Suite 1510, New York, New York 10018, Tel. No. (212) 971-0416, so that the present application can receive an early notice of allowance.

In light of the foregoing, the application is now believed to be in proper form for allowance of all claims and notice to that effect is earnestly solicited.

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